



WORKING WITH CHPSO: NAVIGATING PRIVILEGES, PROTECTIONS AND REPORTING REQUIREMENTS

California Hospital Patient Safety Organization

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Overview of Teleconference

- How to create effective systems to gather, evaluate and use information for normal hospital and medical staff operations while participating in a PSO;
- How to share information with a PSO without jeopardizing other available protections and privileges; and
- How to maintain and utilize information that may be needed for other purposes – such as peer review or reporting to other agencies, in light of some of the constraints imposed by the Patient Safety and Quality Improvement Act of 2005*

“White Paper”

- A white paper has been posted on the CHPSO website that discusses in greater detail the various issues that we will be covering in today’s teleconference.
- Welcome comments and questions – will be a Q&A period at the end of this presentation.

Key components of the Act

- PSO – Patient Safety Organization
 - CHPSO has been “listed” as a PSO by the Secretary of HHS
- PSES – “the collection, management, or analysis of information for reporting to or by a PSO”
 - One of the issues we will be discussing is whether these are the only activities that can be conducted within a PSES

- PSWP – will spend some time reviewing the definition of PSWP
 - which as many of you have undoubtedly discovered, is a rather convoluted and arguably inconsistent definition
 - but if we read it in consonance with the purposes of the Act,
 - it is actually a broad definition
 - that invites exploration of the possibilities for reconfiguring conventional hospital and medical staff QI activities
 - many of which QI activities are, in essence Patient Safety Activities --
 - and merging them into an overall system that encompasses both the PSES and standard QI activities

Creating the PSES

- Will talks some about:
 - How is it done?
 - Can it subsume normal QI activities?
 - or vice-versa – i.e., can normal QI activities subsume the PSES?
 - Can there be more than one in a hospital?

Privileges

- Will discuss the privileges that attach to PSWP – namely protection from:
 - Administrative subpoena or order
 - Discovery
 - Admission as evidence in any state or federal, civil or criminal proceedings (with exceptions)
 - Admission in a professional disciplinary proceeding (which is the source of much consternation)
 - Disclosure (pursuant to FOIA or similar state law)

Provider Authorizations

- Will be discussing whether hospitals can gain additional maneuverability through these rules by effective use of provider authorizations
 - Provider-specific authorizations operate as an exception to the Privileges

Overview of How It Works

- Hospitals create PSESs
- The PSES is where the hospital houses its PSWP
- The PSWP garners all of the privileges and protections of the Act as soon as it enters the hospital's PSES – even before it has been reported to the PSO
- Within – or outside – the PSES, the hospital can use the PSWP to conduct a variety of PSAs
- Until PSWP is reported, the hospital can de-designate information as PSWP, and use it for other, inconsonant purposes
 - Upon de-designation, it loses its PSWP privileges and protections
- Once reported to the PSO, the PSWP privileges and protections are locked in
 - And at this point, it can no longer be de-designated and used for inconsonant purposes

PSES means

- The collection, ***management***, or ***analysis*** of information for reporting to a PSO.
- This is, in essence, a virtual system – a “working harbor” – and it’s where the hospital “houses,” manages, and analyzes its own PSWP
- While a hospital is not legally required to document the structure of its PSES, documentation is strongly recommended (in the commentary to the final rule)

To document a PSES, hospital must first determine its “structure” – i.e., how does it relate to other systems in the hospital – most particularly, its standard QI functions?

- Is it something hospital does alongside its standard QI activities – i.e., discrete PSES and QI functions?
- Does the hospital house some or all of its QI within the PSES?
- Or does the hospital house its PSES within its standard QI functions?

Structuring the PSES (cont'd)

- It is not clear whether the hospital is permitted to house all QI activities *within* its PSES (though it could house those aspects of standard QI that involve PSWP)
- It does, however, appear, to me, possible to house all of the hospital's PSES within the hospital's standard QI functions

For visual thinkers - Envision it like a balloon within a balloon

- The outer balloon is your standard QI system
- The inner balloon is your PSES system
- Here, the inside balloon will take up however much of the volume inside the outer balloon as you decide to fill it with

- With that as your visual

- the portions of the outer balloon that are not filled by the inner balloon represent those aspects of QI functions that cannot take place within the PSES, and that cannot utilize PSWP

- Adding a bit to this visual

- the inner balloon has some release valves, that permit it to release PSWP into the outer balloon when and if the outer balloon needs to use that information
- [once it's released and de-designated, it is no longer PSWP]

One final visual to consider

- May be possible to stuff more than one PSES balloon inside the bigger QI system balloon
 - which as I've suggested in the white paper, might serve as a model for creating more than one PSES [or perhaps these are separate compartments of a single PSES]
 - in any case, these may be areas of the inner balloon that are managed by different constituencies within the hospital – such as the medical staff



In considering whether this balloon will fly...

- The FR commentary (at page 70740)*

By offering providers the ability to examine patient safety event reports in the patient safety evaluation system without requiring that all such information be immediately reported to a PSO, and by providing a means to remove such information from the patient safety evaluation system and end its status as patient safety work product, **the final rule permits providers to maximize organizational and system efficiencies and lessens the need to maintain duplicate information for different needs.**

But they do caution:

We note, however, that a provider should not place information into its PSES unless it intends for the information to be reported to the PSO.

- They reiterate (at p. 70742)

Such information may be voluntarily removed from a patient safety evaluation system if it has not been reported and would no longer be patient safety work product. **As a result, providers need not maintain duplicate systems to separate information to be reported to a PSO from information that may be required to fulfill state reporting obligations. All of this information, collected in one patient safety evaluation system,** is protected as patient safety work product unless the provider determines that certain information must be removed from the patient safety evaluation system for reporting to the state. Once removed from the patient safety evaluation system, this information is no longer patient safety work product.

Documenting the PSES

- White paper, at § IIA (page 3) includes recommendations for what should be included in documenting the PSES – including
 - statement of intent
 - here my recommendation is that you specifically incorporate appropriate language from the definition of PSA
 - also recommend using this broad description of PSA in describing the *hospital's* QI function
 - namely being sure its overall broader purposes include [though need and should not limited to] the same functions conducted within the PSES

What might these include? – see definition of PSA – 4 of 8 PSA are particularly relevant:

- Efforts to improve patient safety and the quality of health care delivery
- The collection and analysis of [PSWP = information which could improve patient safety , health care quality, or health care outcomes]
- Development and dissemination of information re: improving patient safety, such as recommendations, protocols, or best practices
- Using information [including PSWP] for encouraging a culture of safety and providing feedback and assistance to effectively minimize patient risk

- These are all purposes that are wholly consonant with the purposes not only of a PSES,
- but also of the QI system itself
- if the hospital adopts these as **part of** its QI purposes, too, then there's no reason to view the information supporting these purposes as information that is "collected, maintained or developed separately, or exists separately, from a PSES."

Drilling down a bit more on documentation of the PSES

- Hospital will need to decide and describe the who, what, when, and how the system will operate
 - what kinds of information will be house in the PSES?
 - will it go there automatically, or will it require a specific contemporaneous decision?
 - how will the reporting be done and to whom?
 - who is authorized to make decisions about information that is in the PSES – e.g., whether it's time to report it on to the PSO, or whether to de-designate it and release it for other uses?
 - what kinds of other activities will be conducted within the PSES – i.e., management and analyses

In doing all of this , you clearly have to focus on PSWP -- the “information” that is at the center attraction for all this activity -- and it is helpful, to revisit the definition of PSWP in light of these analytical balloons that we’ve been using for purposes of cyber-illustration – to assess more specifically how much PSWP you’re going to put into your PSES:

- § 3.20 of the rule defines PSWP as:

- data, reports, records, memoranda, analyses (such as RCA), or written or oral statements
- which could improve patient safety, health care quality, or health care outcomes
- which are assembled or developed for reporting to the PSO and which are reported
- [or are not yet reported but are documented as within the PSES, including date of entry into the PSES]

§ 3.20 also describes what is *not* PSWP (this is what has created so much consternation)

- PSWP does not include:
 - original records
 - medical records, billing records, other original patient or provider information
 - information collected, maintained, or developed separately, or existing separately, from a PSES
 - here, the more integrated the hospital's QI and PSES are, the easier it is to reconcile what is and is not PSWP, and avoid what might otherwise seem to call for duplicative or parallel information management systems.

Then, having focused on what PSWP is, the hospital still gets to decide...

- Decide what kinds of information will be designated as its PSWP
- Decide when you will enter that into your PSES
 - Will it be before you've assessed what other, inconsonant needs you may have for the information?
 - Or will you enter it into the PSES, and then decide you have other needs for it, and remove it [let it out through one of the balloon's escape valves] so you can use it to meet those other needs?
- Consider early entry – even if it just makes a “touch and go landing” – because most PSWP will not be required for inconsonant uses
 - Most of the information can be used by the hospital, for its *internal* QI purposes and other operational requirements, without having to be released through the escape valve
 - And, even information that you know, or anticipate may be needed for other uses [such as disciplinary peer review], can rest in the inner balloon – and while it's there, remain protected – until and unless it is needed for inconsonant purposes

The critical qualifier is: good faith intent to ultimately report the information to the PSO

- The information does not have to be **actually** reported to the PSO to enjoy the protections provided by the Act
- but indefinite harboring will be suspect
 - [Particularly if that is where most of your PSWP forever rests]
- Include in your system policies:
 - criteria for periodically assessing and deciding when/if to report it to the PSO
 - as well as whether release it from the PSES and de-designate it as PSWP



Conducting PSA - and *other uses of PSWP* - within the hospital

- The PSES can do more than simply house PSWP
- Within it, you can conduct your own PSA – i.e., you **manage** and **analyze** the information
- And, because the hospital is permitted to make other **internal*** uses of PSWP, you can conduct your normal QI functions, using your PSWP – **whether you do so within or outside your PSES**
- Most normal QI functions can be done **either** within the PSES balloon, or they can be done in the outer [omnibus] QI balloon
 - **consonant uses** can make use of PSWP, even that PSWP which has already been reported to the PSO – and can be conducted in either arena [or balloon]
 - **inconsonant uses** require that PSWP not yet have been reported, and that it be de-designated and removed from the inner balloon of the PSES



Consonant v. Inconsonant Uses

- Consonant Uses ***[those that are not a disclosure and not prohibited]***
 - PSA
 - QI [except professional discipline]
 - Other hospital operations [internal uses only – not external reporting requirements]
 - Permitted disclosures [e.g., to hospital’s attorneys...]*

- Inconsonant uses ***[either a disclosure or are prohibited]***
 - Professional discipline
 - External reporting
 - Litigation
 - Other external uses
 - Exception: if information is sufficiently “nonidentified” (as relates to providers) or “de-identified” (as relates to patients), **

How can PSWP be used for peer review?

- As noted in WP, there has been some commentary (both in the final rule and by AHRQ in its outreach activities), suggesting that virtually all in-hospital peer review (even the disciplinary aspects of it) can be done using PSWP.
- I don't agree with that – and I know many of you attorneys listening in on this call do not either – because of the way the Act and the final rule are worded
 - namely, there is a prohibition from using PSWP in any “professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law.”
 - AHRQ apparently intended to be referring only to external disciplinary bodies, but their wording went overboard.
 - in California, the B&P reporting laws, and hearing requirements squarely place hospital peer review proceedings within the description of a “professional disciplinary body authorized under State law.”

Peer review

- That said, I think it is possible to:
 - conduct routine peer review [OPPE/FPPE], using PSWP
 - inside or outside the PSES balloon [no need to release the PSWP to use it outside the balloon for consonant purposes]
 - and if necessary to use it for disciplinary action, release the PSWP and use it – so long as it has not been already reported to the PSO
 - important to establish criteria for harboring PSWP that may be needed for peer review
 - don't want rules that require you to release the information if not used within a specific time frame
 - [e.g., like some MS Bylaws provisions that require adverse information to be removed from a physician's credentials file if no action is taken within a stated period of time]
 - you don't know when you may need it

- if have inconclusive information
 - either continue to harbor it
 - or consider removing it from PSWP
 - creating, at that time, a parallel set of information, segregating originals of what you may need for peer review
 - and assembling a separate packet [not a duplicate] of reconstituted information to be entered back into the PSES as PSWP and reported on to the PSO
- if information has already been released
 - do have option to redevelop information from original or alternative sources

Other personnel actions

- Don't have the constraint of having to conduct a “professional disciplinary proceeding” by a “professional disciplinary body”
- Don't have the reporting requirements that compel you to release hearing record to the professional licensing agency
- So in theory, could take internal disciplinary actions, using PSWP, whether or not the PSWP had been reported to the PSO
- Advise against this – because of potential for employee filing a complaint and hospital needing to use the PSWP in its defense
- Unless you are certain you've outwaited the S/L, or otherwise settled the matter in a way that you're sure you won't need the PSWP, then you should handle these matters similarly to the way suggested for medical staff disciplinary matters.

Privileges and Protections

- Act itself provides for a number of privileges - § 3.204, and at p. 11 of WP
 - Subpoena
 - Discovery
 - Disclosure (FOIA) and similar state laws
 - Admissibility in any court [including federal]
 - Admissibility in any professional disciplinary proceedings
- These are substantially broader than any other available protections – they apply
 - in administrative arenas
 - in federal arenas
 - in criminal arenas (with some exceptions)
- While these protections should not be the tail wagging the dog [either to get you into the PSO system – or to keep you out of it (because the protections may cause their own issues) – they do certainly are important incentives and features of this process

These are in addition to any privileges or protections under State law

- Evidence Code section 1157 protection – is it lost by reporting information to the PSO?
- Good arguments can be made that it is not lost
 - California cases, cited in WP, supporting the basic premise that because 1157 is a protection (or more specifically a rule aimed at “evidence affected or excluded by extrinsic policies”) – it is not subject to waiver by disclosure
 - Particularly helpful is the *Henry Mayo Newhall* case, where the court found that a disclosure that was **consistent with the purposes of the statute** did not cause a loss of the protection
 - none of the cases that I reviewed are on all 4s with our situation, but they certainly build good pillars for asserting that reporting to a PSO is consistent with the purposes of the statute [which is to foster full and frank discussion in furtherance of improving care and protecting patients] and does not cause loss of 1157 protection
 - reporting to the PSO is, in essence, to get more professional peers reviewing and weighing in on the implications of what happened – how to correct it, how to develop or derive best practices

Why even worry about 1157 protection, since PSA privileges are so much broader?

- If hospital decides to report non-PSWP [e.g., de-designated PSWP] to the PSO because they determine it serves higher purposes to do so
- Or, if litigator successfully claims that information was not properly classified as PSWP in the first place [e.g. because it was created for other purposes], 1157 protection should still be available to protect the information
- Recommend that 1157 protections be asserted in transmitting 1157 information to the PSO

Attorney-client privilege

- Incident Reports [when structured as part of A/C communications]
- A/C discussions within the PSES or QI system
- here, too, why worry if PSO protection is so much broader?
 - so long as information maintains its PSWP, this will hold true and adequately protect the information
- But, unless hospital intends to waive it's A/C privilege and rely solely on PSWP Privilege, do not sent A/C communications



External reporting

- Required reporting such as Adverse Event Reporting – cannot use PSWP
- Voluntary report to TJC (or other accrediting body) – e.g., of RCA
 - Can be done, using PSWP, ***with any identified provider's authorization****
 - consider including such an authorization in your application form:

→e.g.,

"Physician acknowledges that from time to time hospital conducts root cause analyses of occurrences in the hospital for the purpose of reducing errors and improving individual and systemic performance.

These root cause analyses are sometimes communicated to hospital accrediting bodies in furtherance of quality improvement.

Physician consents to communication of root cause analysis results to hospital accrediting bodies, with the understanding and subject to the condition that such accrediting body may not further disclose this information."

- at this point, I would not try to use disclosures to authorize Adverse Event reporting – simply because the Act and final rule commentary so specifically state that PSWP cannot be used in this way

- but it does beg the question, whether it might be possible to use authorized disclosure as means to conduct in-hospital disciplinary actions AND to report those actions and release that information to the MBOC?
 - it is a bigger stretch

 - but note that authorized disclosures are permitted exceptions to the privileges, and it might be possible to get a physician willing to do that if he/she knows that discipline is inevitable, and that federal litigants are waiting in the wings
 - footnoted this idea in the WP, not as a recommendation, because I'm not convinced myself that it would work [but it does keep gnawing on me as a possibility]

Q&A

Questions?

- Contact me at:

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